

Cp / 1623/8

Attorney Docket No.: PTI-001CN

N 2 /2 /2-01

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

RECEIVED

APPLICANT:

Kornblith

FEB 0 5 2003

SERIAL NO.:

09/040,161

GROUP NO.:

1623

TECH CENTER 1600/290

FILING DATE:

March 17, 1998

EXAMINER:

Gitomer, R.

TITLE:

Method for Preparing Cell Cultures from Biological

Specimens for Chemotherapeutic and Other Assays

CERTIFICATE OF FIRST CLASS MAILING UNDER 37 C.F.R. 1.8

I hereby certify that this correspondence, and any documents referred to as enclosed herein, are being deposited with the United States Postal Service as first class mail, postage prepaid, in an envelope addressed to the Commissioner for Patents, Washington, DC 20231 on this 31th day of January, 2003.

Jeremy P. Oczek

Commissioner for Patents Washington, D.C. 20231

RECEIVED

FFR 4-4-2003

Sir:

Submitted herewith are:

AND INTERFERENCES

- 1. Supplemental Information Disclosure Statement (2 pgs.);
- 2. Form PTO-1449 (3 pgs.);
- 3. Copies of References as Cited A1-A16, B1 and C1-C30;
- 4. Transmittal Form (1 pg.);
- 5. Fee Transmittal (1 pg.);
- 6. Check in the amount of \$180.00; and
- 7. Return Receipt Postcard.

| | (1) | | | | | | |
|---------------------------------------|---|---|--|---|----------------------|---|-------------------------------|
| | CEB 0 3 MAD SE | Application | n Serial Number | | 940,161 | | |
| | EB D 3 E E | Filing Date | | Mai | March 17, 1998 RECEI | | |
| | \\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\ | | First Name | ed Inventor | Kor | nblith | |
| | TRANCE TTA | λL. | Group Art | Unit | 1623 | 3 | FEB n 5 2 |
| | FODM | | Examiner 1 | Name | Gito | omer, R. TE | CH CENT |
| | FORM | | Attorney D | Oocket No. | PTI | -001CN | CH CENTER 10 |
| | | | Patent No. | | Not | applicable | |
| | | | Issue Date | | Not | applicable | |
| | | Eï | NCLOSURES (6 | check all that apply) | ···.' | | |
| ▼ Fe | e Transmittal Form | | Copy of Notic | ce to File Missing cation (PTO-1553) | | Notice of Appeal | to Board and Interferences |
| | ☐ Check Attached☐ Copy of Fee☐ Transmittal Form | | Formal Drawi | , | | Appeal Brief (in | |
| | Amendment/Response | | Request For C Examination (| | | Status Inquiry | |
| | ☐ Preliminary ☐ After Final | | Transmittal | | ∣⊠ | Return Receipt P | ostcard |
| | Affidavits/declaration(s) Letter to Official Draftsperson | | Power of Atto (Revocation o | orney of Prior Powers) | | Certificate of First under 37 C.F.R. | st Class Mailing |
| | including Drawings [Total Sheets] | | Terminal Disc | claimer | | Certificate of Fac Transmission und | |
| | Petition for Extension of Time | | | laration and Power or Utility or Design ation | | Additional Enclo (please identify b | |
| ⅓ | Supplemental Information Disclosure Statement | | Small Entity S | Statement | | DEALN | |
| Form PTO-1449 Copies of IDS Citations | | | CD(s) for large table or computer program | | RECEIVED | | |
| | Certified Copy of Priority | | Amendment A | After Allowance | | FEB:30 | 2003 |
| | Document(s) Sequence Listing submission Paper Copy/CD Computer Readable Copy Statement verifying identity of above | | Request for Correction Correction Certificate duplicate) | ertificate of e of Correction (in | | ARD OF PATEN AND INTERF E F | |
| CORR | ESPONDENCE ADDRESS | | | SIGNATURE BL | OCK | | |
| Direct a | Patent Ac Testa, Hu High Stre 125 High Boston, N Tel. No.: Fax No.: | rwitz & 7 et Tower Street 1A 0211 (617) 248 | Γhibeault, LLP 0 8-7000 | Date: January 31, 2 Reg. No. 50,794 Tel. No.: (617) 310 Fax No.: (617) 248 | -8158 | Jeremy P. Oczek Attorney for App Testa, Hurwitz & High Street Towe 125 High Street Boston, MA 021 | licant Thibeault, LLP |

FEB 0 3 2002

| | Complete if Known | |
|---------------------------|-------------------|-------------|
| Application Serial Number | 09/040,161 | REO |
| Filing Date | March 17, 1998 | ''LUEN' |
| First Named Inventor | Kornblith | |
| Group Art Unit | 1623 | FEB 0.5 |
| Examiner Name | Gitomer, R. | - 70p3 |
| Attorney Docket No. | PTI-001CN | IECH CENTER |

| FED | | Attorney | Docket No. | | 1-001CIV | VIED 1000 |
|----------|--|-----------|---|------------|---|---------------------|
| 3/2 | METHOD OF PAYMENT | | | FEE C | CALCULATION (continued) | u 160 0 |
| No. | Payment Enclosed: | | 3. ADDITIO | | | |
| ı. X | Check Money Order Other | Large | Small | | 1 | |
| | _ | | Entity | Entity | 5 5 14 | Fee Paid |
| 2. 🛛 | The Commissioner is hereby authorized to cre | edit | Fee | Fee | Fee Description | ree raio |
| - | or charge any fee indicated below for this sub | omission | (\$) | (\$) | | |
| | to Deposit Account No. 20-0531. | | 120 | 65 | Surcharge - late filing fee or oath | |
| | Required Fees (copy of this sheet enclo | | 130 | 25 | Surcharge - late provisional filing fee | |
| | Additional fee required under 37 CFR | 1.16 and | 50 | 23 | or cover sheet | |
| | 1.17. | | 130 | 130 | Non-English specification | |
| . 🖂 | Overpayment Credit. | | 2,520 | 2,520 | Request for ex parte reexamination | |
| 3. 🛛 | Applicant claims small entity status. FEE CALCULATION | | 110 | 55 | Extension for reply within first month | |
| . 1777.7 | | | 400 | 200 | Extension for reply within second | |
| ı. PILI | NG FEE | | | • | month | |
| Large | e Entity | | 920 | 460 | Extension for reply within third month | |
| Fee (| - | Fee Paid | 1440 | 720 | Extension for reply within fourth | |
| Ì | | | 10.00 | 000 | month Extension for reply within fifth month | |
| | | | 1960 | 980 160 | Notice of Appeal | |
| 740 | | | 320 320 | 160 | Filing a brief in support of an appeal | —— |
| 330 | ~ ~ | | 280 | 140 | Request for oral hearing | |
| 160 | Provisional filing fee | L | 130 | 130 | Petitions to the Commissioner | |
| | | | 180 | 180 | Submission of Information Disclosure | |
| | Number Number Rate | Amount | | | Statement | |
| | Filed Extra | | 740 | 370 | Filing a submission after final | |
| | | | 1 | | rejection (37 CFR 1.129(a)) | |
| Total Cl | aims $-20 = x \$ 18.00 =$ | | 740 | 370 | For each additional invention to be | |
| | - | | | | examined (37 CFR 1.129(b)) | <u> </u> |
| Indepen | | | 100 | 100 | Certificate of Correction for applicant's error | ! |
| Clain | -3 = x \$ 84.00 = | | Other fee (Spe | rify) | Supplemental Information Disclosure | \$ 180.00 |
| | tiple Dependent Claim(s), if any \$280.00 = | | Other ree (Spe | , | Statement | |
| ⊔ Mult | tiple Dependent Claim(s), if any \$280.00 = | | | | | 1 |
| | TOTAL: | 0.00 | Ç | | | |
| | SMALL ENTITY DISCOUNT: | | AND | | | |
| | SUBTOTAL (1) (\$) | 0.00 | | | I | |
| 2. AM | ENDMENT CLAIM FEES | ь | 불유 | H | SUBTOTAL (3) (S | 5) 180.00 |
| | Claims Highest No. Present Rate | Fee Paid | 77 | B 3 | SUBTOTAL (3) | ,, 100.00 |
| | Remaining Previously Extra | | 33 3 | | - m | |
| Α | fter Amend. Paid For | | OF PATENT APPEALS | - | | 60.00 |
| Total | = x \$ 18.00 = | | R | ~ | SUBTOTAL (1) | |
| Indep. | - = x \$ 84.00 = | | "Z> | 2003 | SUBTOTAL (2) SUBTOTAL (3) | |
| | st Presentation of Multiple Dep. + \$280.00 = | = | Q { | , 3 | SOBIOTAL(3) | Ψ 100.00 |
| Cla | iim TOTAL: | (\$) 0.00 | SC | 1 | | L |
| | SMALL ENTITY DISCOUNT: | (\$) 0.00 | | _ | | |
| | SUBTOTAL (2) | (\$) 0.00 | 1 " | , | TOTAL (\$) 1 | 80.00 |
| | | | | | SIGNATURE BLOCK | |
| | CORRESPONDENCE ADDRESS | | <u> </u> | | Respectfully submitted, | |
| Direct | all correspondence to: | | | | $(1 \mathcal{D}\lambda)$ | |
| | Patent Administrator | 110 | Date: January | | Jeany 1. Oak | 2 |
| | Testa, Hurwitz & Thibeault, | LLP | Reg. No.: 50, | | Jegemy P. Oczek | |
| | | SITERI | Tel. No.: (617) 310-8158 Attorney for the Applicant | | | |
| | High Street Tower-125 High | Street | Tel. No.: (61' | 7) 310-815 | | |
| | Boston, MA 02110 | | Tel. No.: (61' Fax No.: (61 | | O Testa, Hurwitz & Thibeaul | t, LLP |
| | | | | | | t, LLP |



PATENT

Attorney Docket No.: PTI-001CN

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

RECEIVED

TECH CENTER 1600/2900

APPLICANT:

Kornblith

SERIAL NO.:

09/040,161

GROUP NO.:

1623

FILING DATE:

March 17, 1998

EXAMINER:

Gitomer, R.

TITLE:

Method for Preparing Cell Cultures from Biological Specimens for

Chemotherapeutic and Other Assays

Commissioner for Patents Washington, D.C. 20231

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Sir:

In accordance with 37 C.F.R. 1.97 and 1.98, Applicants hereby make of record the patents and publications listed on the accompanying Form PTO-1449 for consideration by the Examiner in connection with the examination of the above-identified patent application. Copies of the patents and publications are enclosed.

REMARKS

This application is on appeal at the Board of Patent Appeals and Interferences.

It is respectfully requested that each of the patents and publications listed on the attached Form PTO-1449, and other information contained herein, be made of record in this application.

Applicants have enclosed the requisite petition fee under 37 C.F.R. 1.17(p) of \$180.00.

02/04/2003 SSESHE1 00000062 09040161

01 FC:1806

180,00 OP

However, should further payment be necessary, the Director is hereby authorized to charge any

such fee to Deposit Account No. 20-0531.

RECEIVED

FEB n 5 2003

TECH CENTER 1600/2900

Respectfully submitted,

Date: January 31, 2003

Tel. No.: (617) 310-8158

Fax No.: (617) 248-7100

Jeremy Oczek (Reg. No. 50,794)

Attorney for Applicant

TESTA, HURWITZ, & THIBEAULT, LLP

High Street Tower 125 High Street

Boston, Massachusetts 02110

FORM PTO - 1449

PAFFORM PTO - 1449

PAFFORM PTO - 1449

EXAMINER

ATTORNEY DOCKET NO.: PTI-001CN

APPLICANT: Kornblith

SERIAL NO.: 09/040,161

TECH CENTER 1600/2900

| PATE | NT & TREE | | U.S. | PATENT I | DOCUM | ENTS | | | | |
|----------------|-----------|------------------------------------|----------------|-----------------|-------------|--------------|----------------|----------------|--|---------------|
| EXAM. INIT. | | DOCUMENT NUMBER | DATE | NAME | <u>-</u> | | CLASS | SUB CLASS | FILING APPROF | |
| | A1 | 4,423,145 | 12-27-1983 | Stampfer et | al. | | 435 | 32 | | |
| | A2 | 4,668,618 | 05-26-1987 | Thornthwai | ite | | 435 | 6 | | |
| | A3 | 4,937,187 | 05-26-1990 | Rotman | | | 435 | 30 | | |
| | A4 | 5,242,806 | 09-07-1993 | Yen-Magui | re et al. | | 435 | 32 | | |
| | A5 | 5,270,172 | 12-14-1993 | Morgan | | | 435 | 29 | | |
| | A6 | 5,443,950 | 08-22-1995 | Naughton e | et al. | | 435 | 1 | | |
| | A7 | 5,607,918 | 03-04-1997 | Eriksson et | al. | | 514 | 12 | | |
| , | A8 | 5,728,541 | 03-17-1998 | Kornblith | | | 435 | 29 | | ا حر |
| | A9 | 5,789,158 | 08-04-1998 | Knowles et | al. | | 435 | 6 | AND O | 5 |
| | A10 | 5,874,218 | 02-23-1999 | Drolet et al | | | 435 | 6 | \\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\ | Ŷ. |
| | A11 | 5,888,765 | 03-30-1999 | Patterson et | t al. | | 435 | 69.1 | B | PAT |
| | A12 | 5,942,385 | 08-24-1999 | Hirth | | | 435 | 4 | <u> </u> | PATENT |
| | A13 | 5,972,639 | 10-26-1999 | Parandoosh | 1 | | 435 | 29 | 2 | r APR |
| | A14 | 6,020,473 | 02-01-2000 | Keyt et al. | | | 536 | 23.1 | S | PEAL |
| | A15 | 6,335,170 | 01-01-2002 | Orntoft | | | 435 | 6 | | S |
| | A16 | 6,416,967 | 07-09-2002 | Kornblith | | | 435 | 29 | | |
| | | <u> </u> | FOREI | GN PATEN | IT DOCU | MENTS | | | | |
| EXAM. INIT. | | DOCUMENT NUMBER | DATE | COUNTRY CODE | CLASS | SUB CLASS | FILING DATE | ABSTR. ONLY | | NGLISH ANG |
| | B1 | WO 96/10742 | 04-11-1996 | wo | | | | | | |
| | - | | OTHER AR | T, JOURN | AL ART | ICLES, E | TC. | | · · · · · · · · · · · · · · · · · · · | |
| EXAM. INIT. | ОТНЕ | R DOCUMENT | 'S: (Including | Author, Title | , Date, Rel | evant Page | es, Place of | Publicati | on) | |
| | C1 | Alley, M., "Mo Sensitivity in S | rphometric and | | - | | | | th and Drug | 3 |

DATE CONSIDERED



FORM PTO - 1449

INFORMATION DISCLOSURE STATEMENT

ATTORNEY DOCKET NO.: PTI-001CN

APPLICANT: Kornblith

SERIAL NO.: 09/040,161

FILING DATE: March 17, 1998 GROUP: 1623

| | | FILING DATE: March 17, 1998 GROUP: 1623 | | | | | |
|----------------|--|--|--|--|--|--|--|
| EXAM. INIT. | OTHER DOCUMENTS: (Including Author, Title, Date, Relevant Pages, Place of Publication) | | | | | | |
| | C2 | C2 Andreotti, P., "TCA-100 Tumour Chemosensitivity Assay: Differences in Sensitivity between Cultured Tumour Cell Lines and Clinical Studies," J Biolumin Chemilumin, vol. 9, pp. 373-378 (1994). | | | | | |
| • | C3 | Broadley, C., et al., "A Tissue-Culture Model for the Study of Canine Vocal Fold Fibroblasts," Laryngoscope, vol. 105, no. 1, pp. 23-27 (1995). | | | | | |
| | C4 | Burczynski, M., et al., "Toxicogenomics-Based Discrimination of Toxic Mechanism in HepG2 Human Hepatoma Cells," Toxicological Sciences, vol. 58, no.2, pp. 399-415 (2000). | | | | | |
| | C5 | Cilley, R., et al., "Fetal Lung Development: Airway Pressure Enhances the Expression of Developmental Genes," Journal of Pediatric Surgery, vol. 35, no. 1, pp. 113-119 (2000). | | | | | |
| | C6 | Dietel, M., et al., "In Vitro Prediction of Cytostatic Drug Resistance in Primary Cell Cultures of Solid Malignant Tumours," Eur J Cancer, vol. 29A, no. 3, pp. 416-420 (1993). | | | | | |
| | C7 | Dudley, D., et al., "A Human Endometrial Explant System: Validation and Potential Applications," Am J Obstet Gynecol, vol. 167, no.6, pp. 1774-1780 (1992). | | | | | |
| | C8 | Frykholm, G., et al., "Heterogeneity in Antigenic Expression and Radiosensitivity in Human Colon Carcinoma Cell Lines," In Vitro Cell Dev. Biol., vol. 27A, pp. 900-906 (1991). | | | | | |
| | C9 | Fulda, S., et al., "Antiproliferative Potential of Cytostatic Drugs on Neuroblastoma Cells <i>In Vitro</i> ," Eur J of Cancer, vol. 31A, no. 4, pp. 616-621 (1995). | | | | | |
| | C10 | Gamboa, G., et al., "Characterization and Development of UCI 107, a Primary Human Ovarian Carcinoma Cell Line," Gynecologic Oncology, vol. 58, pp. 336-343 (1995). | | | | | |
| | CH | Ghosh, A., et al., "Immunohistological Staining of Reactive Mesothelium, Mesothelioma, and Lung Carcinoma with a Panel of Monoclonal Antibodies," J Clin Pathol, vol. 40, pp 19-25 (1987). | | | | | |
| | C12 | Goldsworthy, T., et al., "Concepts, Labeling Procedures, and Design of Cell Proliferation Studies Relating to Carcinogenesis," Environmental Health Perspectives, vol. 101, supp. 5, pp. 59-66 (1993). | | | | | |
| | C13 | Gress, T., et al., "Development of a Database on Transcribed Sequences in Tumour Cells and Identification of Changes in Transcription Patterns Related to Transformation and Other Tumour Cell Properties for the Global Finger Printing Analysis of Human Pancreatic Carcinoma cDNA Libraries," Biomed 1. Health Res., vol. 24, pp. 171-181 (1998). | | | | | |
| | C14 | Hoffman, R., "The Three-Dimensional Question: Can Clinically Relevant Tumor Drug Resistance be Measured <i>In Vitro</i> ?" Cancer and Metastasis Reviews, vol. 13, no. 2, pp. 169-173 (1994). | | | | | |
| | C15 | Kaaijk, P., et al., "Daunorubicin and Doxorubicin but not BCNU have Deleterious Effects on Organotypic Multicellular Spheroids of Gliomas," British Journal of Cancer, vol. 74, no. 2, pp. 187-193 (1996). | | | | | |
| | C16 | Kitamura, M., et al., "Chemosensitivty of Gastric Cancer Using Adhesive Tumor Cell Culture System," Oncology Reports, vol. 2, no. 1, pp. 27-31 (1995). | | | | | |
| EXAMIN | NER | DATE CONSIDERED | | | | | |



| | | FEB () 3 2003 | ATTORNEY DOCKET NO.: PTI-001CN APPLICANT: Kornblith SERIAL NO.: 09/040,161 FILING DATE: March 17, 1998 GROUP: 1623 | | | | |
|----------------|--|---|---|--------------|--|--|--|
| FORM I | PTO - 1 | 1449 | ATTORNEY DOCKET NO.: PTI-001CN | V | | | |
| INFORM | /ATIC | ON DISCLOSURE STATEMENT | APPLICANT: Kornblith | <i>่</i> 00ว | | | |
| | | | SERIAL NO.: 09/040,161 | ر . م | | | |
| | | | FILING DATE: March 17, 1998 GROUP: 1623 | 10/2 | | | |
| EXAM. INIT. | OTHER DOCUMENTS: (Including Author, Title, Date, Relevant Pages, Place of Publication) | | | | | | |
| | C17 | Kornblith, P., "Role of Tissue Culture in Pr. 346-376 (1978). | rediction of Malignancy," Clinical Neurosurgery, vol. 25, pp. | | | | |
| | C18 | Kornblith, P., et al., "Variations in Respons Neurosurgery, vol. 48, no. 4, pp. 580-586 (| se of Human Brain Tumors to BCNU <i>In Vitro</i> ," Journal of (1978). | | | | |
| | C19 | Nance, K., et al., "Immunocytochemical Pa Effusions," Am J Clin Pathol, vol. 95, pp. 8 | anel for the Identification of Malignant Cells in Serous 867-874 (1991). | | | | |
| | C20 | Persons, D., et al., "Interphase Molecular C American Journal of Pathology, vol. 142, n | Cytogenetic Analysis of Epithelial Ovarian Carcinomas," no. 3, pp. 733-741 (1993). | | | | |
| | C21 | | ity of Keratin Proteins in Formalin-Fixed, Paraffin-Embedded n," Journal of Histochemistry and Cytochemistry, vol. 33, no. 5, | | | | |
| | C22 | | stochemical Evidence of Squamous Metaplasia from the thology, vol. 17, no. 3, pp. 272-275 (1990). | | | | |
| | C23 | Singh, H., et al., "Significance of Epithelia Effusions," Diagnostic Cytopathology, vol. | al Membrane Antigen in the Work-Up of Problematic Serous . 13, no. 1, pp. 3-7 (1995). | | | | |
| | C24 | | of γ-Interferon Production by Peripheral Blood Mononuclear Clin. Exp. Immunol., vol. 65, pp. 396-400 (1986). | | | | |
| | C25 | Stewart, R., et al., "Glutamate Accumulation Brain Research, vol. 118, no. 3, pp. 441-45 | on By Human Gliomas and Meningiomas in Tissue Culture," (2 (1976). | | | | |
| • | C26 | Stoop, J., et al., "Identification of Malignant Cells in Serous Effusions Using a Panel of Monoclonal Antibodies Ber-EP4, MCA-b-12 and EMA," Cytopathology, vol. 3, pp. 297-302 (1992). | | | | | |
| | C27 | Wiseman, I., "A Modification of Hepatest, Donors," J Clin Pathol, vol. 29, no. 3, pp. 2 | using the Terasaki Plate, for the Detection of Hb _S Ag in Blood 264-266 (1976). | | | | |
| | C28 | International Search Report for PCT/US01/ | /32540 dated April 18, 2002. | | | | |
| | C29 International Search Report for PCT/US9 | | /11595 dated August 17, 1998. | | | | |
| | C30 | International Search Report for EP 97 93 3 | 267 dated May 3, 2002. | | | | |
| | | | RECEIVED FEB 1 2003 | | | | |
| · | | | - 1 2003 | | | | |
| EXAMIN | ER | | DATE CONSIDERED DATE CONSIDERED INTERFERENCES | | | | |